UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA ex rel. TIMOTHY CRAWLEY, Plaintiff, -against- COLUMBIA UNIVERSITY IN THE CITY OF NEW YORK, and LAURA A. JOHNSTON, PhD, Defendants.	21 CV 1153 (ER)(JLC) QUI TAM COMPLAINT DEMAND FOR JURY TRIAL Filed under seal pursuant to 31 U.S.C. § 3730(b)(2)

COMPLAINT AND DEMAND FOR JURY TRIAL

1. This is a civil action by relator Timothy Crawley ("Relator") on Relator's own behalf and on behalf of the United States of America ("United States") against Columbia University in the City of New York ("Columbia"), and Laura A. Johnston, PhD ("Johnston") (jointly, "Defendants"), under the *qui tam* provisions of the False Claims Act, 31 U.S.C. § 3729 *et seq*. ("FCA"), for treble damages, per claim/per false statement penalties, reasonable attorneys' fees, litigation expenses and costs, and other relief, arising from Defendants' fraudulent application for, and receipt of, research grant funds, directly or indirectly, from the National Institutes of Health ("NIH") from approximately January 2003 to the filing of this complaint.

NATURE AND OVERVIEW OF THE ACTION

2. As set forth more fully below in this complaint, Defendants engaged in blatant research misconduct and, in doing so, violated the FCA by fraudulently applying for and receiving research funds from NIH in connection with approximately 26 grants, ranging in amounts from

$201,250 to $400,362, as well as three administrative supplements, and aggregating approximately, $8.4 million, to which they were not entitled, either in full, or in the specific amounts sought and obtained.

3. More specifically, from approximately January 2003 to the filing of this compliant, Defendants knowingly submitted applications and reports (or the equivalent) to NIH containing materially false and fraudulent statements, representations and material omissions concerning laboratory data, including, the incorporation by reference of scientific journal articles written and published by Johnston or her associates containing similarly false and misleading data. Truthfully reporting Johnston's laboratory findings would have undercut the premise underlying all of her research projects, and, accordingly, the basis for Defendants' receipt of NIH grant support.

4. As a result of the above-described activities, the United States has suffered significant economic losses, the precise amount of which will be determined at trial.

JURISDICTION

5. The Court has subject matter jurisdiction over the federal claims alleged in this complaint under 31 U.S.C. § 3732(a) (False Claims Act), 28 U.S.C. § 1331 (federal question), and § 1345 (United States as plaintiff, should it choose to intervene in the action).

6. The Court has personal jurisdiction over Defendants pursuant to 31 U.S.C. §3732(a) because Defendants can be found, reside, and transact business in this District, and because an act proscribed by 31 U.S.C. § 3729 occurred within this District. Section 3732(a) further provides for nationwide service of process.

VENUE

7. Venue is proper in this District under 28 U.S.C. §§ 1391(b) and (c), and 31 U.S.C. § 3732(a) in that Defendants reside and transact business, and a substantial part of the events or omissions giving rise to the violations of 31 U.S.C. § 3729 alleged in this complaint occurred in this District.

PARTIES, ENTITIES, AND INDIVIDUALS

8. The United States, through the NIH, is the real party in interest in the *qui tam* claims in this action.

9. NIH is a part of the U.S. Department of Health and Human Services ("HHS"). NIH is the nation's principal medical research agency — seeking to make important discoveries that will improve health and save lives. NIH achieves its mission by, among other things, offering funding for many types of academic research grants, contracts, and educational loan repayment for researchers. NIH's headquarters are located at 9000 Rockville Pike, Bethesda, Maryland 20892.

10. NIH is comprised of a number of institutes and centers that support specific areas of health-related research. There are approximately 20 NIH institutes that focus on discrete areas of medical research. These include three institutes that have been defrauded by Defendants through the scheme alleged in this complaint, namely: the National Cancer Institute ("NCI"), located at 37 Convent Drive, Bethesda, Maryland 20814; the National Institute of General Medical Sciences ("NIGMS"), located at 45 Center Drive MSC 6200, Bethesda, MD 20892-6200; and the National Institute of Child Health and Human Development ("NICHD"), located at 6710 Rockledge Dr, Bethesda, MD 20817.

11. NCI, the primary instituted affected by Defendants' fraudulent activities, leads a national effort to eliminate suffering and death due to cancer. Through basic and clinical biomedical research and training, NCI conducts and supports research leading to the prevention of cancer before it starts, identifying cancers that do develop at the earliest stage, eliminating cancers through innovative treatment interventions, and biologically controlling cancers that cannot be eliminated so they are transformed into manageable, chronic diseases.

12. NCI achieves its mission, by, among other things, offering academic research funding in the form of Non-Competing Awards and Competing Awards. NCI relies on peer review evaluation of scientific merit as the primary consideration in its funding decisions. Such peer review decisions are made by NCI Scientific Program Leaders ("SPLs") following discussions with NCI program staff. NCI also supports early career investigators and gives special consideration to funding applications that fill a significant gap in the cancer research portfolio or propose an especially novel or promising scientific approach.

13. NIH, NCI, NIGMS and NICHD are among the various HHS Public Health Service ("PHS") Awarding Components, also known as, PHS agencies, PHS funding components and PHS funders. PHS establishes and enforces regulations governing the application for, and receipt of, PHS funding.

14. The Office of Research Integrity ("ORI"), within the HHS Office of the Assistant Secretary for Health ("OASH"), oversees and directs research integrity for all PHS biomedical or behavioral research and research training activities, except for regulatory research integrity activities overseen by the Food and Drug Administration ("FDA"). ORI is located at 1101 Wootton Parkway, Suite 240, Rockville, Maryland 20852.

15. Relator, whose true identity has been provided to the U.S. Attorney's Office for the Southern District of New York, is a PhD student in the field of cellular & molecular biology, and a graduate research assistant, who, from in or about September 2016, to on or about July 12, 2019, worked at Columbia as a research assistant for Johnston while enrolled as a graduate student in Columbia's Integrated Program in Cellular, Molecular and Biophysical Sciences. Relator voluntarily transferred out of Johnston's laboratory in the summer of 2019 after he uncovered and reported serious research misconduct. Relator currently works in a different laboratory at Columbia.

16. Relator is also a "complainant," within the meaning of PHS regulation 42 C.F.R § 93.203, because he in good faith made allegations of "research misconduct," within the meaning of PHS regulation 42 C.F.R. § 93.103 (namely, "fabrication," "falsification" or "plagiarism") against Johnston to representatives of Columbia in 2019, including, professors Ronald K. Liem, PhD, Donna L. Farber, PhD and Lloyd Greene, PhD, and Naomi Schrag, Esq., Vice President for Research Compliance, Training, and Policy, and Michael A. Klein, Esq., Director of Research Compliance.

17. Columbia is an educational university for undergraduate and graduate students studying in many scholarly and professional fields, as well as a prominent American research center. Columbia's Office of the President is located at 535 West 116th Street, MC 4309, New York, New York 10027.

18. Columbia is a so-called "Tier One Research University," and relies heavily on federal agencies (including, NIH), private foundations, and city and state agencies to finance its research efforts, including, for paying the salaries of research staff who do not engage in teaching activities.

19. Columbia oversees, supervises and administers its faculties' application for and use of NIH funding from various offices within the university. Columbia's Office of Research Initiatives ("CU ORI") helps identify opportunities and strategies for obtaining research funding from these sources. CU ORI is located at room 409A in Columbia's Low Memorial Library. Columbia's Sponsored Projects Administration ("SPA") serves as a central resource to support Columbia's research community by providing guidance and stewardship for the researchers and administrators on all Columbia campuses. SPA operates through the delegation of authority from the University Board of Trustees as a unit of the Office of the Executive Vice President for Research, which is located in room 313 of Columbia's Low Memorial Library. SPA, through a designated Project Officer ("PO") reviews all applications before they are submitted to funding sponsors, including NIH. Columbia's Sponsored Projects Finance ("SPF") is part of the Office of the Controller and is the university's central office responsible for managing key elements in the post-award financial administration of sponsored projects. SPF is comprised of an Executive Director and three teams (Operations, Letter of Credit and Cash Accounting) that are responsible, respectively, for managing all aspects of SPF, handling all department-facing aspects of post-award financial administration, managing the letter-of-credit drawdown or reimbursement process and quarterly reporting of letter of credit projects to the federal government, and processing and applying payments received for sponsored projects, and for managing collections activity on outstanding receivables. SPF is located within Columbia's Finance Department at 615 West 131st Street, Studebaker Building · New York, NY 10027. Columbia's Office of Research Compliance and Training ("ORCT") is supposed to ensure Columbia faculty, students and staff are in compliance with all regulatory requirements governing research. ORCT also administers Columbia's Standing Committee on the Conduct of Research, which addresses issues of research

misconduct. OCRT is located in Office of the Executive Vice President for Research in room 313 of Columbia's Low Memorial Library. Lastly, the Vagelos College of Physicians and Surgeons ("VP&S") Office for Research facilitates biomedical research, from basic to translational to clinical, among the VP&S faculty, students, and staff at Columbia University Irving Medical Center. The Office for Research, including through its Pre-Award Core unit, works across departments, centers, and institutes to foster interdisciplinary research collaborations, and supports efforts to secure funding for such collaborations. The Office for Research is located at 630 West 168th Street, Physicians & Surgeons, 15-402, New York, NY 10032.

20. Columbia is also an "institution," within the meaning of PHS regulation 42 C.F.R. § 93.213, because Columbia applies for or receives PHS support for an activity or program that involves the conduct of biomedical or behavioral research, biomedical or behavioral research training, or activities related to that research or training. As a PHS institution, Columbia is required by the terms of 42 C.F.R. § 93.307, when applicable, to conduct an "inquiry," within the meaning of 42 C.F.R. § 93.212, and an "investigation," within the meaning of 42 C.F.R. § 93.215, of credible allegations of research misconduct concerning PHS funding, and to report these allegations to ORI. Such reporting must be done via Form PHS 6349 (Institutional Assurance and Annual Report on Possible Research Misconduct), or the equivalent, and must comply with PHS reporting regulations, including, the requirement that the Form PHS 6349 be signed and certified by an official of the institution.

21. Columbia was required to conduct an inquiry and investigation of Relator's allegations of research misconduct concerning Johnston and report the allegations on Form PHS 6349 and the results of its investigation to ORI.

22. Johnston is a professor in the Department of Genetics & Development at Columbia University Medical Center and a member of Columbia's Herbert Irving Comprehensive Cancer Center and the Columbia Stem Cell Initiative. At all times relevant to this complaint, Johnston was (and continues to be) a project director ("PD") and principal investigator ("PI") on many NIH-funded research grants and contracts and engaged in minimal teaching activities at Columbia. Johnston's research laboratory (the "Johnston Lab") was, and still is, located at 701 W. 168th St. HHSC 704. New York. NY. 10032.

23. Generally, Johnston's principal field of research is the interplay between genetics and development, with a further interest in how developmental processes may resurface during cancer. More specifically, according to Johnston's page on Columbia's website, at all times relevant to this complaint, the Johnston Lab sought to investigate the mechanisms used by growing tissues to gauge and regulate the collective and individual fitness of cells, thereby optimizing tissue and animal fitness. Johnston was particularly interested in the basic biological mechanisms that regulate these processes, how they contribute to development of healthy tissues and in understanding their relevance to developmental and tumorigenic pathologies. Johnston used the simple genetic model organism Drosophila and utilized strategies that allowed manipulation of growth and cell fitness in living, growing animals. Johnston's research projects included: how the growth regulator Myc mediates competitive interactions during tissue and organ growth; investigation of homeostatic processes, including metabolism, that allow cells to sense and respond to growth changes in their local environment; identification of factors that act as sensors and mediators of cellular fitness; and genetic and molecular dissection of tissue regeneration. These processes provide plasticity to growing organs and give cells control over their local environment.

24. From in or about January 2003, to on or about March 30, 2020, NIH/NCI, awarded or renewed a total of approximately 26 grants and three administrative supplements to Johnston. These grants and supplements were intended to promote research goals.

LIABILITY UNDER THE FCA

25. The FCA as amended on May 20, 2009, imposes civil liability on "any person" who, among other things:

> (A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;
>
> (B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim;…or
>
> (G) knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government.

31 U.S.C. §§ 3729(a)(1)(A), (B) and (G) [amended May 20, 2009].

DEFINITIONS IN THE FCA'S LIABILITY SECTION

26. For purposes of the FCA, "knowing" and "knowingly" mean that a person, with respect to information: (i) has actual knowledge of the information; (ii) acts in deliberate ignorance of the truth or falsity of the information; or (iii) acts in reckless disregard of the truth or falsity of the information, and no proof of specific intent to defraud is required. 31 U.S.C. § 3729(b)(1).

27. For purposes of the FCA, "claim" means any request or demand, whether under a contract or otherwise, for money or property and whether or not the United States has title to the money or property, that (i) is presented to an officer, employee, or agent of the United States; or (ii) is made to a contractor, grantee, or other recipient, if the money or property is to be spent or

used on the Government's behalf or to advance a Government program or interest, and if the United States Government (I) provides or has provided any portion of the money or property requested or demanded; or (II) will reimburse such contractor, grantee, or other recipient for any portion of the money or property which is requested or demanded. 31 U.S.C. § 3729(b)(2)(A) (as amended May 20, 2009; the prior version is materially identical for purposes of this action).

28. For purposes of the FCA, "obligation" means an established duty, whether or not fixed, arising from an express or implied contractual, grantor-grantee, or licensor-licensee relationship, from a fee-based or similar relationship, from statute or regulation, or from the retention of any overpayment. 31 U.S.C. § 3729(b)(3).

29. For purposes of the FCA, "material" means having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property. 31 U.S.C. § 3729(b)(4).

DAMAGES, PENALTIES AND AWARDS UNDER THE FCA

30. The FCA imposes liability on any person violating Section 3729 to the United States as follows: a civil penalty of not less than $5,000 and not more than $10,000, as adjusted by the Federal Civil Penalties Inflation Adjustment Act of 1990 (28 U.S.C. § 2461 note; Public Law 104–410), plus three (3) times the amount of damages which the United States sustained because of the act of that person. 31 U.S.C. § 3729(a)(1).

31. Where the Government proceeds with an action commenced by the filing of a *qui tam* complaint and recovers money from a defendant under Section 3729, the person who initiated the action (the "relator") may receive up to twenty-five percent (25%) of the proceeds. Where the Government does not proceed with such an action and the relator pursues it on his/her own and recovers proceeds from a defendant under Section 3729, the relator may receive up to thirty percent

(30 %) of the proceeds. In either case, the relator is also entitled to an award against the defendant for the amount of all reasonable expenses, attorneys' fees and costs. 31 U.S.C. § 3730(d).

NONE OF THE FCA'S BAR PROVISIONS IS APPLICABLE

32. Upon information and belief, none of the bars set forth in the FCA's *qui tam*-related provisions, 31 U.S.C. §§ 3730(b)(5) and (e) is applicable to this action.

33. Upon information and belief, no person other than the Government has brought a related action based on the facts underlying this complaint. 31 U.S.C. § 3730(b)(5).

34. This action is not brought by a former or present member of the armed forces under 31 U.S.C. § 3730(b) against a member of the armed forces arising out of such person's service in the armed forces. 31 U.S.C. § 3730(e)(1).

35. This action is not brought against a Member of Congress, a member of the judiciary, or a senior executive branch official. 31 U.S.C. § 3730(e)(2).

36. Upon information and belief, this action is not based on allegations or transactions which are the subject of a civil suit or an administrative civil money penalty proceeding in which the Government is already a party. 31 U.S.C. § 3730(e)(3).

37. Upon information and belief, none of the allegations or transactions as alleged in this action or claim were publicly disclosed via the following channels: (i) in a Federal criminal, civil, or administrative hearing in which the Government or its agent is a party; (ii) in a congressional, Government Accountability Office, or other Federal report, hearing, audit, or investigation; or (iii) from the news media. 31 U.S.C. § 3730(e)(4)(A).

38. In addition to the foregoing allegation, Relator is an "original source," as defined in the FCA, 31 U.S.C. § 3730(e)(4)(B), because: (1) prior to a public disclosure under 31 U.S.C.

§§ 3730(e)(4)(A)(i)-(iii), Relator voluntarily disclosed to representatives of the United States Attorney's Office for the Southern District of New York the information on which the allegations or transactions in this complaint's claims are based; and/or (2) through his employment by Columbia in the Johnston Lab Relator has knowledge that is independent of and materially adds to any publicly disclosed allegations or transactions, and Relator voluntarily provided the information to representatives of the United States Attorney's Office for the Southern District of New York before filing an action under the *qui tam* provisions of the FCA. 31 U.S.C. §§ 3730(e)(4)(B)(1) and (2).

FCA'S STAUTE OF LIMITATIONS

39. A civil action under section 3730 of the FCA may not be brought: (1) more than 6 years after the date on which the violation of section 3729 is committed; or (2) more than 3 years after the date when facts material to the right of action are known or reasonably should have been known by the official of the United States charged with responsibility to act in the circumstances, but in no event more than 10 years after the date on which the violation is committed, whichever occurs last. 31 U.S.C. § 3731(b).

NIH FUNDING PROGRAM

40. NIH awards research grants through various funding mechanisms.

41. The Research Project Grant (as known as, the "R01") is the original and historically oldest grant mechanism used by NIH. R01 grants provide funding for health-related research and development based on the mission of the NIH. An R01 grant is awarded to support a discrete, specified, circumscribed project to be performed by the named investigator(s) in an area representing the investigator's specific interest and competencies, based on the mission of the NIH.

R01s can be either investigator-initiated or can be solicited via a Request for Applications ("RFA"). For investigator-initiated R01 grants, the research plan proposed by the applicant must be related to the stated program interests of one or more of the NIH institutes and centers based on their missions.

42. R01 grants are generally awarded for one to five budget periods, each normally 12 months in duration. They can be renewed by competing for an additional project period.

43. R01 grants cover certain costs ("Allowable Costs"). These include: salary and fringe benefits for Principal Investigator ("PI"), key personnel, and other essential personnel; equipment and supplies; consultant costs; alterations and renovations; publications and miscellaneous costs; contract services; consortium costs; Facilities and Administrative ("F&A") indirect/overhead costs; and travel expenses.

44. In order to be awarded an R01 grant the applicant must submit a completed application to an NIH funding agency. The completed application will include, but is not limited to, a Project Summary, describing the goals of the proposed research and relevance to public health; a Budget; a summary of the Institutional Environment and resources available at the institution; a Biographical Sketch stating the experience and qualifications of the applicant; and, Specific Aims, a concise explanation of the proposed research, with briefly stated goals for the research. The heart of the application is contained in the Research Strategy. This section provides:

a. Background information necessary to understand the proposed research;

b. Information regarding the importance of the proposed research to public health.;

c. A summary of preliminary data collected by the applicant that prompted the desire to perform the research proposed. Preliminary data can come in the form of both references to and

exhibition of the lab's previous published work, as well as exhibits of unpublished data generated by the lab; and

d. A detailed plan for the course of research proposed in the aforementioned "Specific Aims." This typically includes an outline of experiments to be performed, the methods to be employed and the manner in which the data will be analyzed to ensure statistical rigor, eliminate bias, and enhance reproducibility.

45. The completed application is reviewed by a panel of scientists from related fields and scored according to the following criteria:

a. Significance: Does the proposed project investigate an important topic in the field and, would the stated aims make important advances to scientific knowledge?

b. Innovation: Does the proposed project seek to shift current research by applying novel investigative techniques, concepts, and/or instrumentation? Would the achievement of the stated aims yield novel investigative techniques, concepts, and/or instrumentation?

c. Approach: Are the proposed methodologies appropriate? Has the investigator indicated strategies to ensure robust and unbiased data? Have potential pitfalls been considered and alternative approaches outlined?

d. Investigator: Does the investigator(s) possess the knowledge, skills, and abilities to successfully carry out the stated research? And,

e. Environment: Will the institutions scientific environment enhance the probability of success?

46. Applications that score well are subject to a Pre-Award Process. During this time, the application is reviewed by the NIH Institute or Center for its alignment with NIH funding principles, the project budget examined, the eligibility of the applicant determined and the

applications compliance with public policy requirements examined. In addition, the application will be assessed for overlap with other funded projects.

47. In anticipation of an award being made, applications in the competitive range for funding are asked to submit Just In Time ("JIT") information for the award. JIT information consists of a list of other support available to the lab, certification of necessary Institutional Review Boards and Institutional Animal Care and Use Committees ("IACUC"). This information is submitted online through the eRA Commons portal.

48. After an R01 grant has been awarded, the grantee is required manage the day-to-day operations of the grant by monitoring grant expenditures and submitting requests for prior approval on any change in scope of the approved project. In addition, the PI is responsible for ensuring the laboratory maintains adequate records of experimental data collected under the purview of the grant.

49. An R01 grant undergoes yearly non-competitive renewals. This process requires that grantees submit a Research Performance Project Report ("RPPR"). The RPPR details accomplishments towards the goals of the project and specifies plans for the following year. In addition, it makes note of any changes, challenges, or delays incurred during the research year. Funding for the subsequent fiscal year is released upon satisfactory completion of the RPPR.

50. At the end of five years, if grantees believe they have achieved or made substantial progress towards the Specific Aims, they can apply for a competitive renewal of the initial R01 grant listing new Specific Aims to be achieved in the following five-year period. The process is substantially similar to the initial R01 grant, and will be scored alongside new applications as well as other competitive renewals. If awarded, the competitive renewal provides an additional five years of funding.

51. NIH also awards grants similar to the R01, including under the "R21" program, which is a grant mechanism designed to encourage exploratory/developmental research by providing support for the early and conceptual stages of project development and the "R35" program, which is intended to give investigators increased freedom to conduct research that breaks new ground or extends previous discoveries in new directions. R35 grants allow PIs to take greater risks and to pursue research that requires a longer timeframe than R01 grants. The application, award and performance processes for R21 and R35 grants are materially the same as those for R01 grants.

PHS RESEARCH MISCONDUCT INVESTIGATION AND REPORTING REQUIREMENTS

52. Institutions applying for or receiving PHS research funding are required to be in full compliance with all of the PHS regulatory requirements.

53. Each institution that receives or applies for a PHS research, research-training or research-related grant or cooperative agreement must have established an administrative policy for responding to allegations of research misconduct that complies with the PHS regulation (that is, 42 C.F.R. Part 93) and certify that it will comply with that policy.

54. Each PHS funded institution is required to file annually a Form PHS 6349. The form requires the institution to affirmatively state (yes/no) whether or not it has established an administrative policy for responding to allegations of research misconduct required by the PHS regulation. (Referred to in this complaint as the, "Section I. Certification.)

55. Form PHS 6349 also requires the institution to affirmatively state (yes/no) whether or not it has received any allegations or conducted any inquiries or investigations of allegations

during the reporting period that: (1) fall under the PHS definition of "research misconduct;" and (2) involve receipt of or requests for PHS funding. (Referred to in this complaint as the, "Section II. Certification.)

56. Under PHS regulations, "research misconduct" means "fabrication," "falsification" or "plagiarism." Each of these terms is further defined as follows:

(a) Fabrication is making up data or results and recording or reporting them..

(b) Falsification is manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record.

(c) Plagiarism is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit. And,

(d) Research misconduct does not include honest error or differences of opinion..

42 C.F.R. § § 93.103.

57. If an institution is required to answer yes to the Section II. Certification, then it is further required to provide details concerning the type of activity, namely, "allegation," "inquiry" or "investigation," which terms are defined as follows:

(a) Allegation means a disclosure of possible research misconduct through any means of communication. The disclosure may be by written or oral statement or other communication to an institutional or HHS official. 42 C.F.R. § 93.201.

(b) Inquiry means preliminary information-gathering and preliminary fact-finding that meets the criteria and follows the procedures of 93.307-93.309. 42 C.F.R. § 93.212.

(c) An inquiry is mandated when: (1) the allegation falls within the PHS definition of research misconduct; (2) the subject matter is within § 93.102 (i.e., involves PHS research

conduct); and (3) the allegation is sufficiently credible and specific so that potential evidence of research misconduct may be identified. 42 CFR § 93.307. And,

(d) Investigation means the formal development of a factual record and the examination of that record leading to a decision not to make a finding of research misconduct or to a recommendation for a finding of research misconduct which may include a recommendation for other appropriate actions, including administrative actions. 42 C.F.R. § 93.215.

(e) An investigation is mandated when: (1) there is a reasonable basis for concluding that the allegation falls within the definition of research misconduct under PHS regulations and involves PHS supported biomedical or behavioral research, research training or activities related to that research or research training, as provided in § 93.102; and (2) preliminary information-gathering and preliminary fact-finding from the inquiry indicates that the allegation may have substance. 42 C.F.R. § 307(c).

58. If a PHS-funded institution is required to answer “yes” to the Section II. Certification on Form PHS 6349, it must also classify the type of misconduct alleged, namely, “Fabrication" "Falsification" or "Plagiarism," as those terms are defined above in this section of the complaint.

59. Every Form PHS 6349 submitted to ORI must be signed by an official of the institution. (Referred to in this complaint as the, “Section V. Certification.”)

60. In addition to filing the Form PHS 6349, the PHS-funded institution must prepare a written inquiry report that meets the requirements of PHS regulations in § 93.307 and § 93.309. 42 C.F.R. § 307(e).

61. The institution must complete the inquiry within 60 calendar days of its initiation unless circumstances clearly warrant a longer period. If the inquiry takes longer than 60 days to

complete, the inquiry record must include documentation of the reasons for exceeding the 60-day period. 42 C.F.R. § 307(g).

62. Within 30 days of finding that an investigation of research misconduct concerning PHS funding is warranted, the institution must provide ORI with the written finding by the responsible institutional official and a copy of the inquiry report. 42 C.F.R. § 93.309.

NIH GRANTS AWARDED TO JOHNSTON/COLUMBIA

63. Between in or about 2003 and in or about 2020, NIH awarded the following grants and administrative supplements to Johnston to be performed at the Johnston Lab located on Columbia's campus and under its oversight and supervision:

(a) 1-R01-HD-042770-01A1, NICHD, Coordination of Growth and Patterning During Development, $357,025 (2003);

(b) 5-R01-HD-042770-02, NICHD, Coordination of Growth and Patterning During Development, $325,464 (2004);

(c) 5-R01-HD-042770-03, NICHD, Coordination of Growth and Patterning During Development, $325,296 (2005);

(d) 5-R01-HD-042770-04, NICHD, Coordination of Growth and Patterning During Development, $317,481 (2006);

(e) 5-R01-HD-042770-05, NICHD, Coordination of Growth and Patterning During Development, $308,105 (2007);

(f) 1-R01-GM-078464-01, NIGMS, Mechanisms of Cell Competition that Regulate Growth During Development, $286,440 (2006);

(g) 1-R01-GM-078464-02, NIGMS, Mechanisms of Cell Competition that Regulate Growth During Development, $240,750 (2007);

(h) 1-R01-GM-078464-03, NIGMS, Mechanisms of Cell Competition that Regulate Growth During Development, $240,750 (2008);

(i) 1-R01-GM-078464-04, NIGMS, Mechanisms of Cell Competition that Regulate Growth During Development, $240,750 (2009);

(j) 3-R01-GM-078464-04S1, NIGMS, Mechanisms of Cell Competition that Regulate Growth During Development, $144,375 (2009-2011);

(k) 1-R21-HD-067918-01A1, NICHD, Novel Signaling Pathway for Tissue Homeostasis, $241,500 (2011);

(l) 2-R01-GM-078464-05A1, NIGMS, Mechanisms of Cell Competition That Regulate Growth During Development, $317,948 (2011);

(m) 5-R21-HD-067918-02, NICHD, A Novel Signaling Pathway for Tissue Homeostasis, $201,250 (2012);

(n) 5-R01-GM-078464-06, NIGMS, Mechanisms of Cell Competition That Regulate Growth During Development, $318,031 (2012);

(o) 5-R01-GM-078464-07, NIGMS, Mechanisms of Cell Competition That Regulate Growth During Development, $307,482 (2013);

(p) 5-R01-GM-078464-08, NIGMS, Mechanisms of Cell Competition That Regulate Growth During Development, $319,267 (2014);

(q) 3-R01-GM-078464-08S1, NIGMS, Mechanisms of Cell Competition That Regulate Growth During Development, $17,336 (2014);

(r) 2-R01-GM-078464-09, NIGMS, Mechanisms of Cell Competition that Regulate Growth During Development, $333,142 (2015);

(s) 1-R01-CA-192838-01, NCI, An Innate System for Detection of Aberrant Tissue Growth, $354,254 (2015);

(t) 5-R01-GM-078464-10, NIGMS, Mechanisms of Cell Competition that Regulate Growth During Development, $333,066 (2016);

(u) 5-R01-CA-192838-02, NCI, An Innate System for Detection of Aberrant Tissue Growth, $362,804 (2016);

(v) 5-R01-GM-078464-11, NIGMS, Mechanisms of Cell Competition that Regulate Growth During Development, $333,026 (2017);

(w) 3-R01-GM-078464-11S1, NIGMS, Mechanisms of Cell Competition that Regulate Growth During Development, $63,520 (2017);

(x) 5-R01-CA-192838-03, NCI, An Innate System for Detection of Aberrant Tissue Growth, $363,142 (2017);

(y) 5-R01-GM-078464-12, NIGMS, Mechanisms of Cell Competition that Regulate Growth During Development, $333,022 (2018);

(z) 5-R01-CA-192838-04, NCI, An Innate System for Detection of Aberrant Tissue Growth, $363,526 (2018);

(aa) 5-R01-CA-192838-05, NCI, An Innate System for Detection of Aberrant Tissue Growth, $353,019 (2019);

(bb) 1-R35-GM-131871-01, NIGMS, Mechanisms of Cell Competition in Growth and Development, $316,286 (2019); and

(cc) 5-R35-GM-131871-02, NIGMS, Mechanisms of Cell Competition in Growth and Development, $400,362 (2020).

FACTUAL ALLEGATIONS CONCERNING DEFENDANTS' SCHEME TO DEFRAUD NIH

64. At all times relevant to this compliant, in connection with her application for, and/or performance under, NIH grants, Defendant Johnston, either directly, or through her research assistants, engaged in the follow research grant misconduct on one or more occasions:

(a) Published images from one experiment as the result of different experiment;

(b) Modified the value of data points subsequent to data collection;

(c) Misrepresented the genetic background in which genetic experiments were performed;

(d) Cropped images in a manner that removed areas contradictory to the favored hypothesis;

(e) Reported results of an experiment, but omitting the fact the positive control failed;

(f) Misrepresented methods of data measurements/analysis;

(g) Performed multiple replicates of an experiment, only reporting instances in which the results matched the favored hypothesis; and

(h) Combined only favorable portions of data from separate experimental replicates to generate the statistically significant results needed for publication. Neither replicate supported the favored hypothesis when analyzed individually, nor when data from both replicates were pooled in their entirety.

65. As illustrative examples of the above practices, NIH-NCI grants 1-R01-CA-192838-01 through 5-R01-CA-192838-05, as well as NIH-NIGMS grants 1-R35-GM-131871-01 through 5-R35-GM-131871-02, are founded on experiments published as, "An Ancient Defense System Eliminates Unfit Cells from Developing Tissues During Cell Competition." Science. 2014 Dec. 5;346(6214), and "Spatially Restricted Regulation of Spätzle/Toll Signaling during Cell Competition." Dev Cell. 2018 Sep. 24;46(6):706-719. In these papers, Johnston claims that less fit cells can be eliminated from developing tissue by activating a certain intracellular molecular pathway. Johnston further claims this process has important implications for human development as well as cancer development.

66. The following list highlights some, but not all, of the fabricated and falsified data contained in the two above-referenced papers:

An Ancient Defense System Eliminates Unfit Cells from Developing Tissues During Cell Competition

(a) Figure 1E presents data to claim that less fit cells receive an elimination signal through specific cell surface receptors. However, to generate data that supports this favored hypothesis, approximately 100 data points are stricken from analysis without explanation, while 20 data points have had their values altered from what was originally collected.

(b) Figure 1C presents data to claim that a certain adapter protein is required to transmit the elimination signal from the cell surface receptor to the interior of the cell. Here again, to generate data supportive of this hypothesis, 47 data points are stricken from analysis without explanation, while 43 data points have had their values altered from what was originally collected.

(c) Supplemental Figures 2A and 2C present data to further support the claim made in Figure 1E. Here again, to generate data supportive of the favored hypothesis, approximately 44

data points are stricken from analysis without explanation, while 41 data points have had their values altered from what was originally collected.

(d) Figure 2A presents data to claim the elimination signal ultimately activates the intracellular protein Rel to initiate death of less fit cells. To do this they present images which claim to show that much less cell death occurs in response to the elimination signal when Rel is mutated. However, the image of the Rel mutant sample is cropped to remove areas exhibiting very high levels of cell death; these cropped out areas directly contradict the claim made.

(e) Figures 3A-3F presents data to further support the favored hypothesis that activation of Rel in response to the elimination signal results in cell death. To do this, they present images purporting to show that increasing the level of activated Rel results in higher levels of the death inducing protein Hid. However, the true results of this experiment, as recorded in microscope images, laboratory notes and lab presentations, showed that increasing the level of activated Rel had no effect on the level of Hid. The data used in the paper instead comes from an experiment wherein the researchers increased the level of activated Rel and then assessed the level of activated Rel in the same cells. As such, the researchers directly fabricated images to support the preferred hypothesis.

Spatially Restricted Regulation of Spätzle/Toll Signaling during Cell Competition

(f) Figure 1E exhibits data used to claim less fit cells can receive the elimination signal through the cell surface receptor Toll-1. The figure presents data combined from two separate experimental replicates. Neither replicate alone indicates Toll-1 is capable of receiving the elimination signal. Nor does the data support this hypothesis when the replicates are pooled together in their entirety. Nevertheless, to generate data supportive of their hypothesis they

combined only favorable portions of the two experimental replicates, in essence manufacturing an ideal data set.

(g) Figures 1F, 2D, 2E, 4H, 4I and Supplemental Figures 5M are used to indicate certain intracellular and extracellular proteins are required for the processing of the elimination signal. However, to generate results supportive of this hypotheses, the researchers collectively struck approximately 330 values from the data sets without explanation (respectively 62, 60, 105, 28, 37, and 37 data points from the figures listed above).

(h) Figure 3C presents data claiming to show the protein Spz is the elimination signal used to rid tissues of less fit cells. The data claims to show there is an increase in the number of dying cells present when they use a genetic line that increases the levels of activated Spz. However, of the three genetic lines used to increase the levels of activated Spz (UAS-Spz*, UAS-Spz^{C106}, and UAS-Spz^{act}), only UAS-Spz^{act} yielded data supportive of the favored hypothesis. The other two genetic lines showed that increasing activated Spz levels had no effect on cell death levels.

(i) Figures 6G-6I presents data from an experiment that uses a well-established assay wherein the experimenter generates marked cell clones, and then measures the size of said clones after a length of time has passed. Here, the assay is used to claim that the elimination of less fit cells requires the presence of certain proteins in the more fit cells. However, the lab notes for these experiments indicate that in several instances only portions of the resulting clones are measured. In the more than fifty years this kind of experiment has been performed there is no precedence for doing this. Nor, is this altered protocol disclosed in the paper. When the partial clone values are excluded, the data once again fails to support the favored hypothesis.

RELATOR'S REPORTING OF RESEARCH MISCONDUCT TO DEFENDANTS

67. On various occasions between in or about March 2019, and in or about July 2019, Relator notified Johnston more than once that he had discovered instances research misconduct in her lab, including, but not limited to, at an in-person lab meeting on or about March 13, 2019.

68. In or about March and April of 2019, Relator advised Columbia, through Relator's graduate program directors (namely, Profs. Liem and Farber), more than once of Johnston's research misconduct, including, but not limited to, at an in-person meeting on April 3, 2019.

69. In or about April of 2019, Relator advised Columbia, through its ORCT compliance officers (namely, Schrag and/or Klein), more than once of Johnston's research misconduct, including, but not limited to, at an in-person meeting on April 12, 2019.

70. Relator was instructed by Columbia employees and representatives to remove from RPPRs Relator had drafted and submitted to Columbia for transmittal to NIH all references to research misconduct he had discovered in Johnson's lab.

71. Upon information and belief, Columbia did not take any remedial steps concerning Relator's "complaint," withing the meaning of PHS regulations, concerning Johnston's research misconduct.

72. Upon further information and belief, Columbia did not conduct an "inquiry" or "investigation," within the meaning of PHS regulations, of Relator's complaint of Johnston's research misconduct, as required by PHS regulations.

73. Upon further information and belief Columbia did not report Relator's complaint concerning Johnston's research misconduct to NIH, including, to ORI via the filing of a Form PHS 6349, as required by PHS regulations.

KNOWLEDGE, MATERIALITY AND DAMAGES

74. Upon information and belief, Defendants knowingly, within the meaning of the FCA, engaged in the above-described conduct.

75. Upon information and belief, Defendants knowingly and wrongfully retained NIH grant funds that they unlawfully received and to which they were not entitled.

76. Upon information and belief, Defendants' above-described conduct was material to NIH's funding decisions concerning Johnston's R01, R21 and R35 grants. Among other things, the Government has pursued and prosecuted similar instances of research misconduct both civilly and criminally. *See e.g.*, *United States ex rel. Thomas v. Duke University*, Case No. 1:17-cv-276 (M.D.N.C. 2019) (Duke University pays $112.5 million to False Claims Act action alleging it submitted applications and progress reports to NIH and EPA containing falsified and fabricated research results); *United States v. Elizabeth Goodwin*, Case No. 10-Cr-112-WMC-01, (W.D. Wis. 2010) (University of Wisconsin researcher convicted of submitting false grant application to NIH containing, among other things, fraudulently manipulated experiment result data, after graduate students exposed research misconduct in her lab).

77. Upon information and belief, Defendants' above-described conduct caused the United States to suffer substantial economic harm.

COUNT 1
False Claims Act Violations
31 U.S.C. §§ 3729(a)(1)(A), (B), and (G)

78. Relator realleges the above allegations as if set forth fully here.

79. This is a claim for treble damages and penalties under the FCA, 31 U.S.C. §§ 3729-32.

80. Through the acts described above and otherwise, Defendants, by and through their employees, agents and representatives, knowingly, or acting with deliberate ignorance and/or with reckless disregard for the truth:

(a) Presented, or caused to be presented, to NIH, false or fraudulent claims for payment or approval concerning Johnston's R01, R21 and R35 grants, all in violation of 31 U.S.C. § 3729(a)(1)(A);

(b) Used, or caused to be made or used, a false record or statement material to a false or fraudulent claim, namely, by submitting the above-described grant applications and research reports, all in violation of 31 U.S.C. § 3729(a)(1)(B). And,

(c) Made, used, or caused to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government, or knowingly concealed or knowingly and improperly avoided or decreased an obligation to pay or transmit money or property to the Government by wrongfully retaining NIH funds to which Defendants were not entitled, all in violation of 31 U.S.C. § 3729(a)(1)(G).

81. Upon information and belief, prior to receiving notice of Relator's allegations, the United States was unaware of the falsity and fraudulent nature of Defendants' false claims and/or the records or statements submitted or made by Defendants to NIH.

82. Upon information and belief, Johnston's false and fraudulent R01, R21 and R35 grant applications and research reports and the records or representations made to NCI, NIGMS and NICHD by Defendants were material to NIH's funding decisions concerning Defendants.

83. By reason of each Defendants' violations of the FCA, the United States has suffered a substantial economic harm in an amount to be determined at trial and is entitled to treble damages and a civil penalty as required by law for each violation.

DEMAND FOR RELIEF

WHEREFOR, Relator, on behalf and in the name of the United States, and on Relator's own behalf under the *qui tam* provisions of the FCA, demands judgment against Defendants as follows:

A. As to Count 1 of the complaint:

(i) Directing Defendants to cease and desist from violating the FCA;

(ii) Awarding damages in the amount of three times the economic loss the United States sustained because of Defendants' actions, plus a civil penalty of $11,000 for each act in violation of the FCA, as provided by 31 U.S.C. § 3729(a) and adjusted by subsequent legislation, with interest;

(iii) Directing Relator be awarded the maximum amount available under 31 U.S.C. § 3730(d) for bringing this action, namely, twenty-five percent (25%) of the proceeds of the action or settlement of the claim if the United States intervenes in the matter (or pursues its claim through any alternate remedy available to the United States, 31 U.S.C. § 3730(c)(5)), or, alternatively, thirty percent (30%) of the proceeds of the action or settlement of the claim, if the United States declines to intervene;

(iv) Awarding Relator all reasonable litigation expenses necessarily incurred in prosecution this action, plus all reasonable attorneys' fees and costs, as provided by 31 U.S.C. § 3730(d). And.

B. Granting such other and further relief to the United States and Relator as this Court deems just and proper.

DEMAND FOR JURY TRIAL

Pursuant to Federal Rule of Civil Procedure 38, Relator hereby demands this case be tried before a jury.

Dated: New York, NY
February 5, 2021

McINNIS LAW,

/s/ Timothy J McInnis
By: _____
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